Supreme Court, U.S.
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No. 95-477

In The

Supreme Court of the United States

October Term, 1995

NOVOPHARM LTD.,

Petitioner,

v.

GLAXO, INC. and GLAXO GROUP LIMITED,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY TO BRIEF IN OPPOSITION

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REPLY TO BRIEF IN OPPOSITION

A. Novopharm Did Everything Possible To Obtain Best Mode Discovery

Glaxo's "facts" regarding the inability of Novopharm to obtain any meaningful pre-trial discovery on the best mode issue are replete with errors. Novopharm did everything possible to obtain that discovery, but was thwarted by Glaxo, and denied relief by the district court. Glaxo, at pages 6-9 of its brief, portrays Novopharm's discovery efforts as fumbling, eleventh-hour acts of desperation, which were properly denied by the district court. Nothing is further from the truth.

Glaxo states that Novopharm received the documents upon which Novopharm was forced to rely for its best mode defense on June 2, 1993. That much is true. Glaxo then argues that Novopharm waited until the eve of trial to attempt to get discovery on the best mode issue, and thus was rightly denied that discovery. That is simply untrue.

As stated previously in Novopharm's Petition, on June 21, 1993, Novopharm filed a motion for summary judgment of invalidity due to Glaxo's violation of the best mode requirement, in which Novopharm asked for discovery on the issue in the event the court was inclined to deny the motion. In response, Glaxo vigorously disputed, *inter alia*, Novopharm's right to bring the motion, insisting that best mode should not be an issue in the lawsuit. While the summary judgment motion was pending, Novopharm attempted to obtain deposition testimony from Mr. Collin, the supervisor of the named inventor, Dr. Crookes, regarding the best mode issue, but was

frustrated in its efforts by Glaxo. (SA 9-14).[1] Therefore, Novopharm had no way to obtain the discovery it desired without intervention from the district court.

On July 20, approximately one week after being rebuffed at the depositions, Novopharm asked the district court to inform Glaxo that best mode was a part of the lawsuit, and that Novopharm was entitled to discovery. Rather than deciding the issue then, with trial fast approaching, the district court took the question under advisement until the pre-trial conference of July 28, 1993, where it ruled that the best mode issue would be tried. The very next day, July 29, 1993, and not August 5, 1993, as Glaxo states (Resp. Br. 8),[2] Novopharm served notices of deposition for Dr. Crookes and Mr. Collin, as well as document requests.

Glaxo attacks Novopharm's attempted discovery as being violative of a host of rules, including that the depositions of Collin and Crookes were noticed for North Carolina. (Resp. Br. 8-9). This argument is irrelevant at best. Novopharm did notice the Crookes and Collin depositions for North Carolina, but did so for a very good reason. At the designated deposition date, counsel for both Glaxo and Novopharm would be in North Carolina preparing for trial. Dr. Crookes and Mr. Collin were also

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[1] References to "SA___" are to the supplemental appendix, which is attached hereto. SA 1 through SA 4 are found in Respondent's Brief in Opposition to Petition for a Writ of Certiorari.

[2] References to "Resp. Br. ___" are to the Respondent's Brief in Opposition to Petition for a Writ of Certiorari.

expected to be in North Carolina, as they were designated by Glaxo as trial witnesses.

Given these facts, the district court erred in denying Novopharm any discovery on the best mode issue, as did the Court of Appeals for the Federal Circuit in affirming that denial. The fact that Novopharm was forced to move quickly on the best mode issue at a time close to the scheduled trial date did not result from any failure on its part. Instead, it resulted from the fact that the district court did not rule on Novopharm's motion to compel until April 27, 1993, *nine months* after the motion was filed, coupled with foot-dragging by Glaxo in producing the documents. Until those improperly withheld documents were received, Novopharm had no basis to even suspect a best mode violation. The district court's refusal to allow any discovery on the best mode issue, and the Federal Circuit's affirmance, penalizes Novopharm for things beyond its control, and is error.

B. Glaxo Affirmatively Chose Not To Present The Testimony Of Dr. Crookes At Trial

With the denial of Novopharm's discovery efforts, the stage was set for trial. There, despite the fact that Novopharm had been allowed no discovery on the best mode issue, Novopharm showed the following, which was adopted by the district court and is not disputed by Glaxo: that (1) Mr. Brereton, Glaxo's in-house patent agent in charge of its Form 2 applications, (2) Mr. Marchant, Glaxo's outside patent agent, and (3) numerous scientists within Glaxo, including Mr. Collin, Dr. Crookes' direct supervisor, knew of Glaxo's best

mode azeotrope granulation technique prior to the filing date of both Glaxo's British and U.S. Form 2 applications. (53a-54a, 56a-57a).

This unequivocal evidence, coupled with Glaxo's failure to allow Crookes, *still a Glaxo employee*, to testify at trial, should have mandated an inference that Crookes also knew. Crookes' absence from the trial was particularly suspect, as he was a designated trial witness *until* Novopharm made the best mode violation an issue for trial.

Glaxo argues that the district court was correct in not inferring knowledge to Crookes, because Glaxo, *Crookes' employer at the time of trial*, did not have the opportunity to present evidence on the best mode issue. Glaxo states that it did not call Crookes to testify because the district court withdrew the best mode issue from the case at the close of Novopharm's case-in-chief. (Resp. Br. 3-4, 12 n.13). Again, this is simply not so.

Glaxo did have an opportunity to present the testimony of Dr. Crookes at trial. The district court only withdrew the best mode issue from the case after Glaxo's lead trial counsel told the district court that Glaxo had nothing to add on that issue. The following interchange is illuminating:

> THE COURT: At the risk of extending this hearing further, I want to ask you a serious question about best mode. If the motion to enter judgment under Rule 52 was denied on best mode, there really isn't anything further that you would put on factually, is there?

* * *

> MR. JUDLOWE: . . . We depending on the dynamics I suppose, make a decision whether we gain anything by putting Dr. Crookes on the stand to repeat it, but I'm not so sure that there's anything of value that would be gained from that.

(SA 7-8).

The above exchange clearly shows that had Glaxo told the district court that Glaxo wanted to have Dr. Crookes testify, the district court would not have withdrawn the best mode issue from the case. Thus, Glaxo did have the opportunity to present Dr. Crookes' testimony at trial, yet made a conscious decision not to do so. The cases cited by Glaxo in its brief (page 12 n.13) are clear that in this situation, the district court could have drawn the inference that Crookes' testimony would have been unfavorable to Glaxo. *Savard v. Marine Contracting, Inc.*, 471 F.2d 536, 541 (2d Cir. 1972), *cert. denied*, 412 U.S. 943 (1973). The district court not only could have made this inference, it should have.

C. The Crookes Declaration Was Essential To Both The District Court's And Federal Circuit's Decisions

Next, Glaxo argues that the non-evidence Crookes Declaration played no part in the decision by the district court to find no best mode violation, or in the Federal Circuit's affirmance of that decision. (Resp. Br. 13-15). Once again, this is simply not so.

The district court, in finding no knowledge on the part of Crookes, credited the testimony of Brereton, who testified, based solely on his reading of the Crookes Declaration, that he did not believe Crookes knew. (56a, SA 5). The testimony on this point is clear and unequivocal:

> Q. Mr. Brereton, to the best of your knowledge, did Derek Crookes have any knowledge of the [best mode]?
>
> A. At the time of this . . . the filing of this case I believe not, *based on his affidavit.*

(SA 5).

The "affidavit" referred to by Mr. Brereton is the Crookes Declaration. Brereton had no other reason for this "belief," because, as he admitted, he had never at any time discussed the best mode issue with Dr. Crookes. (SA 6).

The district court, equally clearly, relied on Brereton's "belief", gained from the Crookes Declaration: "Brereton testified . . . it was his belief that Crookes did not know . . . . " (56a). The district court, by crediting Brereton's testimony on the issue of Crookes' knowledge, therefore improperly gave weight to the Crookes Declaration, without hearing from Crookes himself, without the Declaration being in evidence, and without giving Novopharm any opportunity to test the merits of that Declaration through either discovery or cross-examination. This is clear error.

Thus, Novopharm took this issue to the Court of Appeals for the Federal Circuit, assuming that the district court's use of the non-evidence Crookes Declaration would be condemned. On the contrary, the Federal Circuit embraced the Crookes Declaration, making it the

centerpiece of its affirmance of the district court on the best mode issue, thereby violating Novopharm's right of due process.

Glaxo's argument that the Federal Circuit did not consider and rely upon the Crookes Declaration borders on the ridiculous. The Federal Circuit majority *quoted* from the Declaration (16a), and the Declaration provided the only support for statements by the majority in its opinion, such as the following:

> Crookes was unconcerned with the commercialization of the claimed compound. It is undisputed that Crookes invented a compound and was not involved in whatever process were to be used to commercially produce it.

(17a). These "facts" come only from the Declaration. (SA 1-4).

Thus, both the district court and the Federal Circuit relied on the non-evidence Crookes Declaration. Glaxo is wrong when it argues to the contrary.

D. Novopharm Was Denied Due Process

To summarize, the following is the scenario that befell Novopharm in the district court and the appellate court. Novopharm, approximately two months before trial, received documents from Glaxo that Novopharm had been seeking for over nine months. Within three weeks of receiving the documents, Novopharm filed a motion for summary judgment on the best mode issue, alternatively asking for discovery. During the pendency of that motion, Glaxo refused Novopharm any discovery on the best mode issue, even directing its deposition

witnesses to not answer any questions related to best mode. The district court then denied Novopharm any discovery on the best mode issue.

At the trial, Novopharm proved that numerous persons at Glaxo, including the patent agent responsible for the application, and Dr. Crookes' supervisor, knew of the concealed best mode. Glaxo then withdrew Crookes from its witness list, and informed the district court that Glaxo would not present any witnesses on the best mode issue.

The district court then found for Glaxo on the best mode issue, stating that Novopharm had failed to prove Crookes knew, relying on Brereton's testimony about the non-evidence, untested Crookes Declaration. On Appeal, the Court of Appeals for the Federal Circuit affirmed, also relying on the Crookes Declaration.

The result of the above is to deny Novopharm its right of due process, and even more importantly, to deny Novopharm the sense that it has been treated fairly and has received "justice" from the court system. If litigants lose confidence that the system works and is fair, the system itself will fail. That is precisely why the safeguards of due process, such as the right of cross-examination, are so important, and so fundamental to our system of justice. Novopharm respectfully asks this Court to recognize those safeguards, which have been ignored by

the district court and the Court of Appeals for the Federal Circuit.

Respectfully submitted,

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* * *

[p. 548] A Yes, it is.

Q And that patent, as it issued, contains claims to pharmaceutical compositions of ranitidine hydrochloride, doesn't it?

A Yes, it does.

Q Specifically claims tablets and other things?

A That's correct.

Q Isn't that true?

A Yes.

Q Now, looking through the specifications of this patent, is this granulation technique disclosed anywhere in the '431 patent?

A No, it's not.

MR. WARD: I have nothing further, Your Honor.

THE COURT: Any cross?

MR. LOCKMAN: Very brief, Your Honor.

CROSS-EXAMINATION

BY MR. LOCKMAN:

Q Mr. Brereton, to the best of your knowledge, did Derek Crookes have any knowledge of the – granulation program Mr. Ward was questioning you about?

A At the time of this – the filing of this case. I believe not, based on his affidavit.

Q And did you at any time ever intend to

* * *

[p. 553] Honor.

THE COURT: All right.

THE WITNESS: Oh, sorry.

THE COURT: Just one second.

THE WITNESS: I'm sorry.

MR. WARD: I'll let you go very soon.

REDIRECT EXAMINATION

BY MR. WARD:

Q At the time the initial British specification was filed for Form 2 ranitidine hydrochloride, prior to that time, had you or anyone else at Glaxo investigated what Dr. Crookes knew about this granulation technique?

A I'm sorry, could you repeat the time frame?

Q Prior to the filing of your British application on Form 2 in 1980, October 1980, did you or anyone else within Glaxo investigate what is fact Dr. Crookes did knew about this granulation process?

A No.

Q Don't you think it would have been a good idea to do that?

A I didn't appreciate that the requirement for best mode was the – the knowledge of the inventor.

Q And how do you have that appreciation today?

A Through the events of this litigation.

Q Now, at the time you believed that the

* * *

[p. 761] Telcom case they cited didn't even discuss the issue, didn't begin to discuss the question of knowledge of the inventor relative to the knowledge of the assignee. And the final case they have referred us to this morning is International Telephone and Telegraph Corporation versus United Carbide, 210USPQ496. Over the lunch hour we were able to extract a copy finding 124, it said, information – quote, information as to the process for making the capacitors beyond the quote without further ado, and quote, reference to dipping by hand, that was the issue, quote, was known to the inventors, end quote.

So in that situation, it obviously is a totally inapposite case because the inventors knew about it there was no question that the inventors not knowing about it.

THE COURT: At the risk of extending this hearing further, I want to ask you a serious question about best mode. If the motion to enter judgment under Rule 52 was denied on best mode, there really isn't anything further that you would put on factually, is there? What I'm trying to get at is, I'm not – this is not a loaded question. It's a very plain and direct question, as I hope all of my questions have been. It seems to me that the best mode issue is one that's [p. 762] going to have to be decided as a matter of law. You've – the facts are not much in dispute. Your witnesses said what they knew, and nobody has made any proof, and they have rested as

to the greater knowledge of the inventor. We're no further along factually on that now than we were at the summary judgment stage, I don't think, and if we aren't, not much of any value could be added factually. You're certainly not going to prove that your inventor knew, and if they haven't, then – and you're not going to disprove that your company knew because the evidence is uncontroverted that they knew. You have your patent man here.

And so whatever the ruling is will be a ruling of law, won't it, ultimately, on this?

MR. JUDLOWE: Your Honor, I – I mean. I don't doubt that the case is entirely – I guess – is an appropriate word. We depending upon the dynamics I suppose, make a decision whether we gain anything by putting Dr. Crookes on the stand to repeat it, but I'm not so sure that there's anything of value that would be gained from that. I don't disagree that the – I mean, I think you're absolutely right. I thing this is an issue of law at this point, and I think it's ripe for decision now. I certainly would be guided by whatever ruling you made now, if you made a ruling.

* * *

CONFIDENTIAL

THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA RALEIGH DIVISION

INDEX No. 91-759-CIV-5-BO

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GLAXO INC. and GLAXO GROUP LIMITED,

Plaintiffs,

-against-

NOVOPHARM LTD.,

Defendants.

----------x

July 8, 1993

DEPOSITION OF JOHN L. WHITE

NEWROCK/DeSIMONE
THE COURT REPORTERS
15 Park Row
New York, New York 10038
(212) 608-3300

[p. 2] July 8, 1993

Deposition of JOHN L. WHITE, taken by Defendant pursuant to 30(b)6 Notice, held at the offices of Hopgood, Calimafde, Kalil, Blaustein & Judlove, Esqs., 60 East 42nd Street, New York, New York, commencing at 11:15 a.m., before Joseph Ravenell, Jr., a Registered Professional Reporter and Notary Public of the State of New York.

NEWROCK/DeSIMONE
THE COURT REPORTERS
15 Park Row
New York, New York 10038
(212) 608-3300

* * *

[p. 8] CONFIDENTIAL – WHITE

the deposition today pending further direction from the Court on the proper scope of discovery.

Again, if the expert testimony is allowed and if Mr. Edelman offers certain opinions and we decided that we want to offer rebuttal opinions at trial from Mr. White, obviously you would have an opportunity to depose on any issues – under all those conditions, then you would have an opportunity to depose on such issues even though you won't have that opportunity today.

I hope that's clear.

MR. WARD: Let me see if I can set the ground rules as I understand it.

You will permit Mr. White to answer questions with respect to the issue of inequitable conduct, the Hunt and Collin declarations?

MR. LOCKMAN: Yes.

MR. WARD: You will not permit any questioning today on whether Glaxo failed to comply with the best mode [p. 9] requirement of Section 112?

MR. LOCKMAN: Not today. Pending further rulings from the Court.

MR. WARD: If I ask a question on that, you will advise the witness not to answer that?

MR. LOCKMAN: Today, that is correct. Pending completion of the briefing and guidance from the Court.

MR. WARD: You will also advise the witness not to answer any questions relating to public use?

MR. LOCKMAN: Yes.

MR. WARD: Is that also the case?

MR. LOCKMAN: Yes.

MR. WARD: Let me see what else I have.

MR. LOCKMAN: Okay.

MR. WARD: I think that's about it.

I understand the ground rules. It's my understanding that the best mode issues in the case, we have different

* * *

In The Matter Of:

Glaxo Inc. v Novopharm Ltd.

David T. Collin
July 15, 1993

Newrock/DeSimone – The Court Reporters
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* * *

[p. 322] COLLIN

MR. WARD: I saw your footnote, but I believe it mischaracterized the relevance. We believe what occurred in 1980 with regard to ranitidine hydrochloride is extremely relevant to the seeding issue. And we will continue to press that position. But for the time being we will not press it with Mr. Collin.

MR. LOCKMAN: Okay.

MR. WARD: While we are on the subject of things that Mr. Collin will not be answering at the deposition, I think we will at some point today run headlong into another one, and that is the issue of what we call the best mode issue, the granulation, the azeotroping granulation issue.

MR. LOCKMAN: Right.

MR. WARD: At this point in time, will you be allowing Mr. Collin to answer any questions that relate to this best mode issue?

MR. LOCKMAN: We are going to [p. 323] take the same position today. Again, you are about to file your response. You have a request for summary judgment, you have a request in the alternative for discovery. I assume the Court will be dealing with that in fairly short order in one form or another and we will comply with the Court's decision. We would like to defer that until we have the Court's guidance on it.

MR. WARD: So if I ask Mr. Collin a question which in your mind relates to best mode, you will advise him not to answer the question?

MR. LOCKMAN: You understand on the basis that I've stated –

MR. WARD: I understand your basis.

MR. LOCKMAN: – that we have objected to this in light of your representations and so forth. And I don't want to narrow what we have said in a lengthy pleading that is before the Court. And we simply await the Court's [p. 324] guidance and reaction to your papers and our response and so forth. Since that should be coming soon, we think it would be more prudent to wait and see what the Court has to say.

MR. WARD: I'm just trying to get the ground rules so we don't waste time with me asking a question that you are not going to allow him to answer and me going through the mechanics of asking him whether he will take your advice.

As long as we have the ground rules set at least for the time being, I won't delve into those areas. So we may see you again.

THE WITNESS: If it's next week I won't be very pleased.

Q. Just remember, I gave you the chance to say it now.

In the 1979 through 1981 time period or to 1981 time period –

MR. LOCKMAN: You are going through year end '80?

MR. WARD: Year end '80.

* * *